Billing Code: 4160-90-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations: Delisting for Cause for Medical

Informatics

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of Delisting.

SUMMARY: AHRQ has delisted Medical Informatics as a Patient Safety Organization (PSO) due to its failure to correct a deficiency. The Patient Safety-and Quality Improvement Act of 2005 (Patient Safety Act) authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity is to conduct activities to improve patient safety and the quality of health care delivery. HHS issued the Patient Safety and Quality Improvement Final Rule (Patient Safety Rule) to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs.

DATES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. The delisting was effective at 12:00 Midnight ET (2400) on June 1, 2012.

ADDRESSES: Both directories can be accessed electronically at the following HHS Web site: http://www.pso.AHRQ.gov/index.html.

FOR FURTHER INFORMATION CONTACT: Eileen Hogan, Center for Quality Improvement and Patient Safety, AHRQ, 540 Gaither Road, Rockville, MD 20850; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; E-mail: pso@AHRQ.hhs.gov.

## SUPPLEMENTARY INFORMATION:

## Background

The Patient Safety Act, Pub. L. 109-41, 42 U.S.C. 299b-21 - b-26, provides for the formation of PSOs, which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. The Patient Safety Rule, 42 CFR Part 3, authorizes AHRQ, on behalf of the Secretary of HHS, to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be "delisted" by the Secretary if it is found no longer to meet the requirements of the Patient Safety Act and Patient Safety Rule. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs.

Medical Informatics failed to respond to a Notice of Preliminary Finding of Deficiency sent by AHRQ pursuant to 42 CFR § 3.108(a)(2) and a Notice of Proposed Revocation and Delisting sent by AHRQ pursuant to 42 CFR § 3.108(a)(3)(iii)(C) which found that Medical Informatics failed to have, within every 24-month period following the PSO's date of initial listing, at least two bona fide contracts with different providers for the purpose of receiving and reviewing patient safety work product, and to notify AHRQ no later than 45 calendar days prior to the last day of the pertinent 24-month period that the PSO has met this requirement. Medical Informatics did not exercise its opportunity to be heard in writing to respond to the deficiencies specified in the notices, and has not provided any evidence of a good faith effort to correct the deficiency. Accordingly, AHRQ has revoked the listing of Medical

Informatics, PSO number P0086, a component entity of Medical Informatics, LLC, effective at 12:00 Midnight ET (2400) on June 1, 2012.

More information on PSOs can be obtained through AHRQ's PSO Web site at http://www.pso.AHRQ.clov/index.html.

Dated: June 19, 2012

Carolyn M. Clancy,

Director

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